UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,521	05/22/2006	Barry R. Lentz	5470-398	4732

20792 7590 10/23/2008

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
KOSAR, AARON J	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,521	LENTZ ET AL.	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 28, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 43-51* is/are pending in the application.

4a) Of the above claim(s) *16-33 and 43-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/08;10/3/07;7/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election **with traverse** of Group I claims 1-15 in the reply filed on July 28, 2008 is acknowledged. The traversal is on the ground(s) that the special technical feature is a soluble phospholipid. Respectfully, this is not found persuasive because the claims recite a phospholipid having solubility, but do not require any solvent, temperature, or degree by which said compositions are "soluble" or a reference composition in which the solubility is measured *or* any minimal structural features which confer solubility to the composition. Thus Applicant's assertion that $C16^{+}$ phospholipids are not soluble or that Triplett's phospholipids are not soluble in an intended use does not preclude Triplett's phospholipid composition from having solubility *per se* (e.g. solubility in supercritical CO_2, DMSO, collidine, etc.) and thus Triplett's phospholipids are still broadly and reasonably embraced by a "soluble phospholipid" to the extent claimed, whereby the instantly claimed phospholipids do not make a contribution over phospholipids of Triplett and thus cannot be a special technical feature. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-33 and 43-51 are pending of which claims 16-33 and 43-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. New claim 51 is dependent upon new claim 50 which is dependent upon withdrawn claim 28. Therefore claims 50 and 51 are grouped in Group VI (claims 28-33) and withdrawn. Claims 34-42 are canceled.

Claims 1–15 are pending *and* have been examined on the merits to the extent of the elected invention.

Claim Objections

Claims 1-15 are objected to because of the following informalities:

In claim 1, step (b), the term "thrombin activation" appears to be an inadvertent typographical error of the term "prothrombin activation" (i.e. conversion of prothrombin to thrombin: page 33, lines 18-19; page 42). Appropriate correction is required.

In claim 10, the term "C6 phosphtidylserine" appears to be a 1,2-dicaproyl-sn-glycero-3-phospho-L-serine (C6PS),

Appropriate correction is required,

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are rejected because the method and the compositions of the steps therein, do not provide for distinguishing the method/compositions from naturally-occurring methods/compositions (e.g. versus the extrinsic/intrinsic clotting cascade *per se*). Please note, however, this ground may be overcome, for example, by identifying the minimal structural features/identity of the components *and/or* providing method steps/transformations which would clearly and unambiguously resolve the instant method/compositions versus that of naturally-occurring processes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a *contacting step* in which the reaction of the sample with the provided reagents necessary for the assay is recited, a *detecting step* in which the reaction steps are effected and quantified or visualized, and a *concluding/correlating step* describing how the results/conclusion of the assay allow for the determination. In these claims, the correlation step is missing, because the conclusion of "detecting thrombin activity...indicative of clotting factor activity" does not clearly and unambiguously correlate the detection and/or indication with an evaluation of clotting activity or how one would discriminate between a positive or negative evaluation (or gradations thereof).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for contact activator species selected from the group consisting of kaolin, clay, silica, CELITE, diatomaceous earth, glass beads, ellagic acid, or combinations thereof, does not reasonably provide enablement for the genus of "contact activators". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded

by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: *(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.*

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method comprising the use of a genus of contact activators; however, the specification provides for a limited number of species of compositions recited as contact activators. Thus, the claims taken together with the specification imply a much greater breadth than is supported by the specification.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Since the species recited are heterogeneous (e.g. ellagic acid (a polyaromatic hydrocarbon(PAH) vs. silicates/silica (clay, kaolin, silica, celite, diatomaceous earth) having no minimal disclosed structural feature, the limited species are not considered representative of the genus. Wherein the genus of activators remains largely unsolved, means for predicting (*a priori* determination) is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high; however, with respect to the *a priori* selection/identification of a composition which qualifies as a contact activator is beyond the purview of one of skill.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

Applicant fails to set forth the criteria that define a "contact activator" other than providing a functional definition of "contact activator" as "particulate and chemical contact activators". Such functional language describes nothing about the chemical, physical or structural properties of these compounds. Attention is directed to General Electric Company *v. Wabash Appliance Corporation* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed.: "the vice of a functional claim exists not only when a claim is 'wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outline goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Claims employing functional language at the point of novelty neither provide those element required to practice the invention, nor "inform the public during the life of the patent of the limits of the monopoly asserted.", *General Electric Co. v. Wabash Appliance Corp.*, at 468.

Thus, insofar as these processes rely on the use of an component "activator" which instead of being characterized by technical features suitable for the identification of the component, is imprecisely defined by means of functional features which merely recite the desired result to be achieved, one would not be apprised as to the compositions embraced by the

term "contact activator", except to the extent of the disclosed species of compositions having said activity.

(8) The quantity of experimentation necessary:

Considering the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make and use the invention to the extent claimed.

It is the Examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-10, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by GEMPELER (**C1-1**:IDS 8/20/2008: WO 01/44493 A2) as evidenced by HÜRTER (**U1**:PTO-892: Hürter, P., et al. "Phospholipids of Red Cells and Blood Plasma in Adults, Newborn Infants, and Patients with Rh Erythroblastosis" Pediatrics 1970 (August) Vol. 46 No. 2, pp. 259-266.).

The claims are drawn to a combining a blood/plasma sample with a phospholipid, a contact activator, and calcium; incubating the mixture; and detecting an activity of Factor Xa or of thrombin.

GEMPELER (**C1-1**) anticipates the claims by teaching a body fluid coagulation-potential assay comprising a body fluid, including plasma; contacting with phospholipids, calcium ($CaCl_2$), and an activator (e.g. RVV-V); incubating at 37 °C; and detecting activity as indicated by optical measurements of clotting (e.g. Example 1, pages 15-16). To the extent that Gempeler

may be silent with respect to the presence/degree thereof of a particular phospholipid, as evidenced by HÜRTER (**U**), plasma intrinsically comprises a degree of phospholipids, including phosphatidylserine (PS) and phosphatidylethanolamine (PE) among others (Hürter, table II). Gempeler teaches that the sample may be a heparinised sample; assayed for factor Xa and thrombin activities; combined with activated protein C or endogenous protein C and activators thereof (e.g. thrombin/thrombomodulin) and assayed for factor V resistance; or other assays (page 16, line 35 through example 2, page 17). Gempeler also teaches that the assay may be provided as a kit comprising an activator, control/calibration samples, and one or more of calcium, plasma, plasma fractions, and coagulation factors (page 13, ¶2). Gempeler also teaches the interrelation of the enzymes/factors in the clotting cascade, including the dependence upon activated protein C (APC) of protein S and the relation/further interdependence upon thrombin, prothrombin, Ca^{+2}, phospholipid, Factor Va, Factor Xa, etc. (figures 1, 4).

Claims 1, 2, 5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by TRIPLETT (**B1-5**:IDS: US 5,705,198 A) as evidenced by HÜRTER (**U1**).

The claims and the teaching of HÜRTER are as presented above.

In general, as evidenced by Hürter plasma intrinsically comprises a degree of phospholipids, including PS and PE.

TRIPLETT anticipates the claims by teaching a method of evaluating clotting activity, including evaluating lupus anticoagulant (LA) activity (e.g. abstract; columns 7-8, examples 4 and 5). Triplett teaches combining a plasma sample; soluble phospholipids, including phosphatidylserine and phosphatidylethanolamine obtainable by extraction or commercially available; a contact activator; and calcium (chloride), including the incubation thereof to activate thrombin/detect thrombin activity (abstract; summary; column 5, ¶ 3,4; examples 4 and 5). Triplett further teaches contacting with normal human plasma and detecting clot formation (e.g. Example 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a), as unpatentable over GEMPELER (**C1-1**) or TRIPLETT (B1-5) and SIGMA (**V1**:PTO-892: Sigma, "Phosphates" Sigma Catalogue, 2000/2001, pages 782-791.) and MATSCHINER (**B1-6**:IDS: US 5,525,478 A) in light of HÜRTER (**U1**).

The claims and the teachings Gempeler or Triplett in light of Hürter (herein referred to as Gempeler/Triplett/Hürter) are as is of record and as provided *supra*.

Gempeler/Triplett/Hürter in general teach a clotting assay, whereas to the extent that Gempeler/Triplett/Hürter may be silent with respect to a concentration or particular degree of hydration (dryness), Gempeler beneficially teaches dry compositions, teaching providing of a lyophilized preparation (e.g. page 9, ¶1). Triplett beneficially teaches drying by teaching reconstitution (e.g. column 5). SIGMA (**V1**) further teaches that the degree of moisture/dilution is a result effective variable in that compositions may decompose at ambient temperature in solution, wherein the phospholipids are commercially available in dry form, including as lyophilized powders stored under argon (e.g. Sigma, "phosphatidylethanolamine", page 788; "phosphatidylserine", page 791). It would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. concentrations/ratios/ proportions of reagents/components; degree of moisture/hydration/dryness of reagents provided), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

To the extent that Gempeler/Triplett/Hürter may be silent with respect to a particular sample identity, it would have been obvious to have used a lupus or a protein S-depleted sample, because Gempeler and MATSCHINER (**B1-6**, column 1, last ¶) respectively teach that lupus and protein S-deficient samples are known. One would have been motivated to have used the test of Gempeler/Triplett/Hürter with other samples including lupus samples or protein S-deficient samples, because Gempeler teaches "preferably conducted on human plasma, but is applicable to

human whole blood (or animal blood or plasma)…for monitoring the effect upon coagulation…in particular inhibitors of factor Xa and/or thrombin (factor IIa), and in particular unfractionated heparin (UFH), low molecular weight heparins (LMWH)…or for a patient suspected of a deficiency or superabundance of one or more blood coagulation components" including lupus (page 10, ¶4- page 11, ¶ 1); and because Triplett teaches that normal plasma and plasma with lupus anticoagulant (LA) associated with lupus and more commonly with secondary infections, drugs, and auto immune diseases (column 1). Furthermore, one would have been motivated to have provided a protein S-depleted plasma, because Matschiner teaches that protein S functions as a blood coagulation component (i.e. essential blood coagulation components involved in the normal down-regulation of blood coagulation) and because functional abnormalities, including protein S-deficiencies, are common to 4-5% of the global population (as protein S- or its upstream protein C-deficiency) and that such persons "should be regularly monitored" (column 1, last ¶ through portion spanning column 2). One would have had a reasonable expectation of success in using a lupus or protein S-deficient sample, because the compositions comprise a common minimal compositional/core chemical components (i.e. plasma); because the samples are known to have use in coagulation cascades and assays; and because success merely requires the contacting and detecting the activity in the compositions, especially in the absence of evidence to the criticality/contrary of some undisclosed feature(s).

Claims 1, 3-5, 7, and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over TANS (**W1**:PTO-892: Tans, G., et al. "Meizothrombin Formation during Factor Xa-catalyzed Prothrombin Activation" The Journal of Biological Chemistry. 1991, 266 (32), pp . 21864-21873.)

TANS teaches defibrinated normal human plasma, adding kaolin and calcium ($CaCl_2$), and incubating at 37°C (e.g. page 21869; methods; figure 7, page 21873). Tans teaches assaying for prothrombin activation via prothrombin activation products, including observing thrombin as the major product (page 21869, ¶1). The composition contains a degree of meizothrombin, wherein "meizothrombin is able to activate protein C with about 75% of the activity of thrombin" (page 21864, ¶1). Tans also teaches contacting a prothrombin sample with a 10μM PS-containing phospholipid (50μM total phospholipid), calcium ($CaCl_2$), and a contact activator (e.g. *E. carnitus* venom); incubation at 37°C; and quantitative analysis of thrombin (assay 1)(e.g. Methods, ¶ 1 (Proteins) and 8 (Quantitative analysis) pages 21865-21866.). As each of the components are obtained/purified from plasma isolates, each of the purified compositions are thus broadly and reasonably interpreted as embracing Protein S depleted plasma. Tans also teaches treatment with heparin (e.g. Figure 4).

To the extent that the instant claims and that of the prior art of GEMPELER/TRIPLETT/ TANS/*et al* (supra) may differ with respect to a sequence of method steps, selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (see, e.g., *Ex parte Rubin*, 128 USPQ 440, 1959, and *In re Burhans*, 154 F.2d 690, 69 USPQ 330 - CCPA 1946) MPEP § 2144.04.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the

forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

The prior art of TANS (supra) is relied upon for the reasons of record above. Please note, the pertinent miniprint text of Figure 7 therein may potentially become illegible upon placement into the Application file. Thus, for the sake of compact prosecution, the excerpt text of Figure 7 is quoted below. Tans (figure 7, page 21873) teaches:

Figure 7. Time course of prothrombin activation during activation of plasma with kaolin in the presence of cephalin (A) and in the presence of collagen stimulated platelets (B).
A. 400μl Defibrinated normal human plasma was preincubated at 37°C with 50μl buffer for 5 min after which 50μl of a Kaolin/cephalin/$CaCl_2$ mixture was added to start activation. Final concentrations reached were: 0.8 volume platelet poor plasma, 25μM cephalin (based on phosphate analysis), 1mg/ml kaolin, 20mM Hepes (pH 7.5 at 37°C) and 13mM added $CaCl_2$. At the time points indicated 10μl aliquots were withdrawn and assayed for prothrombin activation products as described in the Experimental Procedures. Symbols represent the, amidolytic activity (arbitrary units) of: ●-●, thrombin; □-□, meizothrombin plus meizothrombin-des-fragment 1; ▲-▲, α2-macroglobulin inhibited products. The highest value of thrombin reached equaled 0.41μM.
B. To 350μl defibrinated normal human plasma 100μl washed human platelets ($1x10^9$/ml) were added and the mixture was incubated at 37°C. After 5 min activation was started with the addition of 54μl of a kaolin/collagen mixture. The reaction was carried out under stirring conditions to ensure optimal expression of platelet procoagulant activity (35). Final concentrations reached were: 0.7 volume platelet poor plasma. $2x10^8$/ml platelets, 10μg/ml collagen, 1mg/ml kaolin, 20mM Hepes (pH 7.5 at 37 °C) and 13mM added $CaC1_2$. At the time points indicated 10μl aliquots were withdrawn and assayed for prothrombin activation products as described in the Experimental Procedures. Symbols represent the amidolytic activity (in arbitrary units) of: ●-●, thrombin; □-□ meizothrombin plus meizothrombin-des-fragment; ▲-▲, α2-macroglobulin inhibited products. The highest value of thrombin reached equaled 0.17 μM.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Aaron J Kosar/
Examiner, Art Unit 1651